

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MINNESOTA**

**CONNECTICUT CHILDREN’S MEDICAL
CENTER, on behalf of itself and all others
similarly situated,**

Plaintiff,

v.

**LUNDBECK, INC. and OVATION
PHARMACEUTICALS, INC.,**

Defendants.

Civil Action No. _____

CLASS ACTION COMPLAINT

JURY TRIAL DEMANDED

CLASS ACTION COMPLAINT

Plaintiff Connecticut Children’s Medical Center (“Connecticut Children’s”) (“Plaintiff”) brings this action on behalf of itself and all others similarly situated, against Lundbeck, Inc. (“Lundbeck”) and Ovation Pharmaceuticals, Inc. (“Ovation”) (collectively, “Defendants”). Plaintiff alleges as follows based upon personal knowledge as to matters relating to themselves, and upon information and belief as to all other matters:

NATURE OF THE CASE

1. This action challenges an anticompetitive acquisition that is forcing hospitals to pay artificially inflated prices for drugs used to treat premature babies born with a potentially life-threatening congenital heart defect known as patent ductus arteriosus (PDA). Indocin and NeoProfen are the only two pharmaceutical treatments for PDA sold in the United States. Lundbeck – which was then named Ovation Pharmaceuticals, Inc. – purchased rights to Indocin in August 2005 and then acquired the

U.S. rights to NeoProfen in January 2006. Plaintiff is a hospital that has purchased Indocin and/or NeoProfen, and is proceeding as a direct purchaser based on assignment of claims from its wholesaler, Cardinal Health, Inc., which bought these drugs directly from Ovation or Lundbeck. Plaintiff seeks to represent a nationwide class of similarly situated entities that purchased Indocin and/or NeoProfen directly from Ovation or Lundbeck from January 2006 until the effects of the challenged anticompetitive conduct cease.

2. At the time Ovation (now Lundbeck, and hereafter called Lundbeck) purchased the rights to Indocin, NeoProfen was awaiting approval by the Food and Drug Administration (FDA). Lundbeck expected that NeoProfen would take a substantial portion of sales from Indocin. To eliminate this competitive threat, Lundbeck acquired NeoProfen.

3. Once it acquired NeoProfen, Lundbeck immediately raised the price it charged hospitals for Indocin nearly 1,300 percent, from \$36 to approximately \$500 per vial. When Lundbeck launched NeoProfen in July 2006, it set a price of approximately \$483 per vial, essentially matching Indocin's price. Lundbeck has profitably maintained prices for the two PDA drugs at or above this artificially inflated level for more than two years.

4. The only alternative treatment for PDA is surgery, which carries a risk of serious complications and costs far more than treatment with drugs. As a result, hospitals have little choice but to pay Lundbeck's artificially inflated price for PDA drug therapy. The artificially high prices that hospitals and other direct purchasers are forced to pay harm consumer welfare more generally.

5. Lundbeck's acquisition of NeoProfen substantially reduced competition and illegally maintained Lundbeck's monopoly in drug treatments for PDA, depriving Plaintiff of the benefits of competition and the lower prices such competition would have brought. As a result of its unlawful acquisition, Lundbeck has obtained and continues to charge artificially inflated prices for Indocin and NeoProfen to Plaintiff and the proposed class.

JURISDICTION AND VENUE

6. This Complaint is filed, and these proceedings are instituted, under Section 4 of the Clayton Act, 15 U.S.C. § 15, to recover threefold damages and the costs of suit and reasonable attorneys' fees, for the injuries sustained by Plaintiff and members of the Class of direct purchasers of Indocin and/or NeoProfen from Lundbeck resulting from Defendants' violations, as hereinafter alleged, of § 7 of the Clayton Act, 15 U.S.C. § 18, and §§ 1 & 2 of the Sherman Act, 15 U.S.C. §§ 1 & 2. The jurisdiction of this Court is based upon 28 U.S.C. §§ 1331 and 1337(a), and 15 U.S.C. § 15.

7. Defendants reside or transact business within this district, committed an illegal or tortious act, have agents, and/or are found in this district. Venue, therefore, is appropriate within this district under 15 U.S.C. § 22, and 28 U.S.C. § 1391(b), (c), and (d).

THE PARTIES

PLAINTIFF

8. Plaintiff Connecticut Children's Medical Center ("Connecticut Children's") is a full service medical center dedicated to improving the physical and emotional health of children of all ages, located at 282 Washington Street, Hartford,

Connecticut 06106, suing under an assignment of claims from Cardinal Health, Inc.

During the Class Period defined below, Connecticut Children's purchased Indocin and NeoProfen from Cardinal Health, Inc., which purchased directly from one or both of the Defendants, and was injured by the illegal conduct described herein.

DEFENDANTS

9. Defendant, Lundbeck, Inc., successor in interest to Ovation, is a privately owned, for-profit Illinois corporation with its headquarters at Four Parkway North, Deerfield, Illinois, 60015. Lundbeck was established on or about March 19, 2009, as a result of the acquisition of Ovation by H. Lundbeck A/S, based in Denmark. Lundbeck sells pharmaceuticals in more than 85 countries, including the United States.

10. Defendant Ovation Pharmaceuticals, Inc. is an Illinois corporation with its headquarters at Four Parkway North, Deerfield, Illinois, 60015. Defendant Ovation was acquired by Lundbeck in March 2009, and sold Indocin and NeoProfen during the class period.

11. Defendants are, and at all relevant times have been, engaged in "commerce" as defined in Section 1 of the Clayton Act, 15 U.S.C. § 12. Defendants' general business practices, the NeoProfen acquisition, and the unfair methods of competition alleged herein are acts "in or affecting commerce."

12. On information and belief, both Ovation and Lundbeck authorized and/or participated in the conduct complained of herein, and are directly liable for the damages incurred by Plaintiff and the proposed class (defined below).

CLASS ALLEGATIONS

13. Plaintiff brings this action under Federal Rules of Civil Procedure 23(a), and 23(b)(3) on behalf of itself and the following class (the “Class”):

All persons or entities in the United States that purchased Indocin or NeoProfen directly from Lundbeck, Ovation, or any of their subsidiaries at any time from January 2006, until the effects of Defendants’ anticompetitive conduct cease (the “Class Period”). Excluded from the Class are Defendants and their parents, employees, subsidiaries, predecessors, successors, and affiliates.

14. Members of the Class are so numerous that joinder is impracticable. Plaintiff believes that the Class includes hundreds of entities, including hospitals or medical centers and pharmaceutical distributors.

15. There are numerous questions of law or fact common to the Class, including:

- a. whether Defendants possess monopoly power;
- b. the definition of the relevant market;
- c. whether, through the conduct alleged herein, Defendants willfully acquired, maintained and enhanced their monopoly power over the non-surgical PDA treatment market;
- d. whether Defendants engaged in unlawful exclusionary conduct to impair the opportunities of potential new entrants or rivals in the non-surgical PDA treatment market; and
- e. whether, and to what extent, Defendants’ conduct caused Class members to pay supracompetitive prices and, thereby, to suffer antitrust injuries.

16. These and other common questions of law and fact predominate over any questions affecting only individual Class members.

17. Plaintiff’s claims are typical of the claims of the Class because all Class members suffered antitrust injury in the same way as a result of Defendants’ wrongdoing,

and the claims of each Class member arise out of the same essential facts and are based on the same legal theories.

18. Plaintiff will fairly and adequately represent and protect the interests of the Class.

19. Plaintiff has retained counsel experienced in class action antitrust litigation, and Plaintiff has no interest in this litigation that conflicts with the interests of the other members of the Class.

20. A class action is superior to any other available methods for the fair and efficient adjudication of this controversy, in that, among other things, such treatment will permit a large number of similarly situated persons to prosecute their common claims in a single forum simultaneously, efficiently, and without the unnecessary duplication of evidence, effort, and expense that numerous individual actions would engender. The benefits of proceeding through the class mechanism, including providing injured persons or entities with a method for obtaining redress on claims that it might not be practicable to pursue individually, substantially outweigh any difficulties that may arise in management of this class action.

21. Plaintiff knows of no difficulty for the Court in managing the claims of the Class that would preclude class certification.

BACKGROUND

22. PDA is a disorder that primarily affects very low birth weight premature infants. In babies with this condition, the blood vessel connecting two major arteries of the heart, the aorta and the pulmonary artery, fails to close on its own soon after birth.

PDA can lead to fatal complications if not treated.

23. The preferred treatment for PDA is drug therapy. Surgery presents a risk of serious complications as well as much higher costs.

24. Hospitals purchase PDA drugs for use in neonatal intensive care units.

25. An estimated 30,000 cases of PDA are treated with drugs in the United States each year.

26. Indocin (indomethacin for injection) was approved by the FDA to treat PDA in infants in 1985. There are no unexpired patents on the product. Until April 2006, Indocin was the only FDA-approved drug for treatment of PDA.

27. In August 2005, Lundbeck purchased rights to Indocin from Merck & Co. Merck agreed to manufacture Indocin and supply it to Lundbeck.

28. Upon acquiring Indocin from Merck, Lundbeck raised the price of Indocin from approximately \$26 to \$36 per vial.

**LUNDBECK ELIMINATES
THE COMPETITIVE THREAT POSED BY NEOPROFEN**

29. When it acquired Indocin, Lundbeck became the only entity selling PDA drug treatment in the United States. But Lundbeck knew that it faced the threat of imminent entry from a rival drug used to treat PDA that was awaiting approval by the FDA, NeoProfen (ibuprofen lysine injectable). Lundbeck expected NeoProfen to take substantial sales from Indocin. Acquiring NeoProfen would eliminate this threat.

30. In January 2006, Lundbeck purchased the U.S. rights to NeoProfen from Abbott Laboratories, Inc. The size of the NeoProfen transaction fell below the regulatory threshold for reporting acquisitions to the federal antitrust agencies. The FDA approved NeoProfen for treatment of PDA in premature infants in April 2006.

LUNDBECK EXPLOITS ITS MONOPOLY POWER

31. Once Lundbeck acquired rights to NeoProfen in January 2006, thereby eliminating NeoProfen as a competitive threat, it promptly raised the price of Indocin nearly 1,300 percent, from approximately \$36 to approximately \$500 per vial.

32. The price at which Merck supplied Indocin to Lundbeck was a small fraction of the \$36 per vial that Lundbeck had previously charged for Indocin.

33. When Lundbeck launched NeoProfen as its second PDA drug in July 2006, it set the price of NeoProfen at slightly below the price of Indocin.

34. Lundbeck has continued to charge prices for Indocin and NeoProfen at or above the level it set for those drugs in 2006.

MONOPOLY POWER

35. Lundbeck, because it now controls the pricing for both Indocin and NeoProfen -- the only two drugs used to treat PDA -- has monopoly power. Lundbeck has demonstrated the ability to profitably sell those products at prices substantially above the competitive level and/or above marginal costs without losing significant sales. Direct evidence of Lundbeck's monopoly power includes Lundbeck's ability to raise the price of Indocin nearly 1,300 percent and to profitably maintain prices for both Indocin and NeoProfen at or above this level for over two years.

36. To the extent it is necessary to show a relevant product market, relevant product market in which to analyze the effects of Defendants' acquisition of NeoProfen is the sale of drugs approved by the FDA to treat PDA.

37. Indocin and NeoProfen are the only two FDA-approved PDA drugs available in the United States. Both products are intravenous formulations of

nonprescription drugs indomethacin and ibuprofen, respectively) and both work to close a patent ductus arteriosus through inhibition of prostaglandin synthesis. Many physicians and hospitals consider Indocin and NeoProfen to be the only reasonably substitutable drugs used to treat PDA.

38. The relevant section of the country, or geographic market, in which to analyze the effects of Defendants' acquisition of NeoProfen is the United States.

39. At all times relevant to the complaint, Lundbeck possessed a 100 percent share of the relevant market. At all relevant times, Lundbeck possessed monopoly power—the ability to profitably raise price significantly above competitive levels without losing significant sales, over the relevant products.

ENTRY BARRIERS

40. Defendants have charged a monopoly price for its PDA drugs for more than two years, and during that time, no competing PDA drug has entered the market.

41. Developing a new drug and obtaining FDA approval to market it in the United States is a costly and time-consuming process that takes substantially more than two years. Entry by a generic version of an existing drug product requires a manufacturer to develop and obtain FDA approval for the generic product. Once a company submits an application, FDA approval of a generic drug takes an average of about 18 months and the approval process can take two years or more.

42. Characteristics of the market for PDA drugs also make entry difficult. With an estimated patient population of 30,000, the PDA drug therapy market is small relative to numerous other pharmaceutical product markets, which limits sales opportunities for any potential new entrant. In addition, the patient population is

exceedingly fragile, and any new entrant must convince physicians who treat premature infants with PDA to forgo use of an existing product with a well-established track record in favor of one that lacks such a history and may present a risk of unanticipated side effects.

43. One company – Bedford Laboratories, Inc. – has FDA approval to sell a generic version of Indocin, but to date it has not entered the market. Bedford received FDA approval for generic Indocin in July 2008.

44. The earliest the FDA could approve a generic version of NeoProfen is 2013, because until then NeoProfen enjoys market exclusivity under the Orphan Drug Act, 21 U.S.C. §§ 360aa-360dd. In addition, two patents claim NeoProfen, the latter of which expires in 2021.

ANTICOMPETITIVE EFFECTS

45. The effects of Defendants' acquisition of NeoProfen include, among other things:

- a. eliminating the expected actual, direct, and substantial competition between Indocin and NeoProfen;
- b. maintaining Defendants' monopoly in the sale of drugs to treat PDA in the United States;
- c. enabling Defendants to exercise monopoly power in the relevant market;
- d. eliminating the competitive constraint that the independent introduction of NeoProfen in 2006 would have placed upon the price of Defendants' first PDA drug, Indocin;

- e. dramatically increasing the price of PDA drug treatment;
- f. raising the cost that Plaintiff and members of the proposed Class pay for drugs to treat PDA; and
- g. harming consumer welfare generally.

46. By acquiring NeoProfen, dramatically increasing the price of Indocin, and pricing NeoProfen to virtually match the Indocin price, Defendants have unlawfully maintained their monopoly and unlawfully profited from its ability to extract monopoly price increases.

47. Had Defendants not acquired NeoProfen, an independent competitor likely would have entered the market, and prices for both Indocin and NeoProfen would have been substantially below the monopoly prices Defendants have charged since January 2006.

48. During the relevant period, Plaintiff and the other Class members purchased substantial amounts of Indocin and NeoProfen. As a result of Defendants' illegal conduct alleged herein, Plaintiff and other Class members paid artificially inflated prices of these drugs. Plaintiff and the other Class members paid prices that were substantially greater than the prices that they would have paid absent the illegal conduct alleged herein. As a consequence, Plaintiff and other members of the Class have sustained substantial damage to their business and property in the form of overcharges.

VIOLATIONS
COUNT I – UNLAWFUL ACQUISITION IN
VIOLATION OF CLAYTON ACT § 7

49. Paragraphs 1-48 above are realleged as if fully set forth herein.

50. Defendants' acquisition of rights to NeoProfen is an asset acquisition within the meaning of Section 7 of the Clayton Act, 15 U.S.C. § 18.

51. The effect of this acquisition has been to substantially lessen competition and to create or maintain a monopoly in PDA drugs for sale in the United States, in violation of Section 7 of the Clayton Act, 15 U.S.C. § 18, and Section 2 of the Sherman Act, 15 U.S.C. § 2.

52. As a result of Defendants' conduct in violation of Section 7 of the Clayton Act, Plaintiff and members of the Class paid artificially inflated prices for NeoProfen and Indocin.

**COUNT II – MONOPOLIZATION IN
VIOLATION OF SHERMAN ACT § 2**

53. Paragraphs 1-52 above are realleged as if fully set forth herein.

54. Defendants have, and at all relevant times have had, monopoly power in the market for the sale of drugs for treatment of PDA in the United States.

55. Defendants willfully maintained their monopoly power by acquiring the U.S. rights to NeoProfen. Eliminating the competitive threat that an independent NeoProfen posed is conduct reasonably capable of contributing significantly to Defendants' maintenance of monopoly power.

56. As a result of securing their monopoly power as described above, Defendants were able to, and did, raise the price of Indocin by nearly 1,300 percent, set the price of NeoProfen therapy at approximately the same level, and have maintained prices at or above this level since 2006.

57. As a result of Defendants' illegal conduct, Plaintiff and the Class paid substantially more than they would have paid for Indocin and NeoProfen.

58. During the relevant period, Plaintiff and the other Class members purchased substantial amounts of Indocin and NeoProfen. As a result of Defendants' illegal conduct alleged herein, Plaintiff and other Class members paid artificially inflated prices of these drugs.

59. There are no legitimate pro-competitive justifications for the conduct alleged herein, and even if there were, the anticompetitive effects would far outweigh any possible pro-competitive effects.

60. Defendants' acts and practices are anticompetitive in nature and tendency and constitute an unfair method of competition, in violation of Section 2 of the Sherman Act, 15 U.S.C. § 2.

**COUNT III – AGREEMENT TO RESTRAIN
TRADE IN VIOLATION OF SHERMAN ACT § 1**

61. Paragraphs 1-60 above are realleged as if fully set forth herein.

62. Defendants entered into an agreement to acquire the U.S. rights to NeoProfen from Abbott Laboratories, Inc., the only other U.S. manufacturer of a pharmaceutical treatment for PDA. Eliminating the competitive threat that an independent NeoProfen posed is conduct reasonably capable of an agreement to restrain trade in contributing significantly to Defendants' maintenance of monopoly power.

63. This agreement was an unreasonable restraint of trade and affected trade in interstate commerce.

64. As a result of entering into the agreement to acquire NeoProfen, Defendants were able to and did, raise the price of Indocin by nearly 1,300 percent, set the price of NeoProfen therapy at approximately the same level, and maintained prices at or above this level since 2006.

65. As a result of Defendants' illegal conduct, Plaintiff and the Class paid substantially more than they would have paid for Indocin and NeoProfen.

66. Defendants have engaged in an unlawful agreement to purchase its only market rival resulting in an unreasonable restraint of trade in violation of Section 1 of the Sherman Act, 15 U.S.C. § 1.

REQUEST FOR RELIEF

WHEREFORE, Plaintiff respectfully requests the following:

- A. Judgment in favor of itself and the Class it seeks to represent and against Defendants, for damages, measured as the overcharges Plaintiff and the other members of the Class paid as a result of Defendants' anticompetitive conduct, trebled;
- B. Pre- and post judgment interest; and
- C. Costs of suit, including reasonable attorneys' fees.

JURY TRIAL DEMANDED

Pursuant to Fed. R. Civ. P. 38(b), Plaintiff demands a trial by jury of all of the claims asserted in this Complaint so triable.

Dated: June 29, 2009

Respectfully submitted,

/s/ Daniel E. Gustafson

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